IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MILLENNIUM LABORATORIES, INC. :
Plaintiff
:
v. Civil Case Nos. L-10-3327
L-12-1753
L-12-1797
:
AMERITOX, LTD.
:
Defendant
:

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MEMORANDUM

I. Introduction

This was a hard contested, but well contested, Lanham Act suit between two competitors in the urine drug testing ("UDT") industry, Millennium Laboratories, Inc. ("Millennium") and Ameritox, Ltd. ("Ameritox"). Each accused the other of false advertising. Midway through trial, after the Court had decided a number of claims, the parties, with the assistance of a United States Magistrate Judge, resolved the remaining issues by agreeing to a Consent Order. See Docket No. 321.

This resolution proved to be only a lull in the hostilities. After the Court formally approved the Consent Order, both sides issued press releases and other public statements concerning the litigation. Each side, taking offense at the other's public pronouncements, filed new Lanham Act lawsuits accusing the other of violating the Consent Order, mischaracterizing the trial, and misstating this Court's rulings. Each suit seeks monetary relief, injunctive relief, and mandatory corrective advertising.

After issuing corrective orders, the Court consolidated the new cases with the earlier suit. In a conference call confirmed by an Order, Docket No. 360, the Court advised the parties that it would issue a Memorandum that neutrally and objectively recounted the earlier litigation. Afterward, the Court would dismiss, with prejudice, the first suit and the newly filed suits.

The Court's decision to summarily dispose of the new suits is based on several propositions. The first involves the Consent Order. While a consent order is a contract between parties to a suit,[1] it is also an order of the court that issued it. The issuing court has authority to resolve any disputes that bear upon its consent order. Moreover, a court has inherent authority to enjoin a party from making misleading statements concerning litigation on its docket. See Am. Sci. & Eng'g, Inc. v. Autoclear, LLC, 606 F. Supp. 2d 617, 626 (E.D. Va. 2008) (ordering removal of a press release that contained misleading statements about the court's rulings). This Court, therefore, has the authority needed to issue a clarifying memorandum.

Second, in the new suits, both sides have prayed a jury trial on all issues. These suits, therefore, contemplate a trial at which a jury would decide what happened in the earlier litigation, including the import of this Court's rulings, and whether the parties' statements violate the Lanham Act.[2] Empaneling a jury to review the extensive history and conduct of the earlier litigation, which included thousands of pages of pleadings, orders, exhibits, and transcripts, would be unconscionably wasteful of both judicial and private resources. For these reasons, this Court and not a jury is the only feasible arbiter of disputes concerning the earlier litigation.

Third, in false advertising cases under the Lanham Act, the characteristic relief is equitable rather than monetary. This follows because of the inherent difficulty in attributing

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[1] See United States v. ITT Cont'l Baking Co., 420 U.S. 223, 238 (1975).

[2] The new suits face at least one threshold legal hurdle. It is problematic whether the press releases constitute "commercial advertising or promotion" under the Lanham Act.

economic injury to a competitor's false advertisements. Either side's effort to prove that the accused press releases caused lost sales or eroded goodwill would necessarily require speculation.[3]

In their new suits, the parties accuse one another of mischaracterizing the earlier litigation. This Memorandum, which recounts the history of that litigation neutrally and objectively, affords both sides with appropriate equitable relief. With the publication of this Memorandum, there is nothing more to decide, the entire case will be at an end, and the Court will dismiss all suits with prejudice.

II. The Earlier Litigation

This Lanham Act case involves allegations of false advertising in the urine drug testing ("UDT") industry. The litigants, Millennium and Ameritox, are competitors. Their laboratories process urine samples using sophisticated equipment. The target audience for their advertisements consists of doctors ("pain doctors") who prescribe powerful opioids such as oxycodone and hydrocodone for patients suffering from chronic pain. Opioids can be a dangerous tool in the doctor's black bag. Studies indicate that as many as 75% of pain patients fail to take their medications as prescribed.

There are many reasons for patient non-compliance. Some patients, afflicted with pain and tempted by the remaining pills in the bottle, take too much. Others sell their pills into the thriving black market for illegal narcotics. Still others, especially the elderly, may simply forget to take their pills, meaning that their pain is not assuaged.

[3] During a conference call, the Court advised counsel of its view that proving damages in the new cases would require speculation. In their subsequent pre-hearing briefing, the parties did not challenge this assessment. See Docket No. 377.

Determining whether pain patients are taking their medication as prescribed poses a problem for pain doctors. Typically, physicians receive little formal training in methods for monitoring their pain patients effectively. Monitoring is also time consuming, requiring periodic office visits during which the doctor might count the patient's remaining pills, examine the patient for physical signs of misuse, and consult with the patient. Such time-consuming monitoring is at odds with the business model (twelve to fifteen minutes per patient) that the pressure of modern medicine has forced on many practices. Insurance further complicates the issue; insurance companies and the government ultimately decide how much monitoring they will pay for, and, therefore, how much monitoring patients will receive.

These difficulties have created a market for an efficient biological test that can assist pain doctors in their efforts to determine whether their patients are prescription compliant. As used in this litigation, the phrase "prescription compliance" means taking the right medication (e.g., hydrocodone) in the right dosage (e.g., a 20 mg tablet) at the right time (e.g., three times per day).

By processing patients' urine samples through sophisticated laboratory equipment, Millennium and Ameritox can provide doctors with considerable information. Their tests can determine the presence (and, by necessary implication, absence) of the prescribed pain medication and a wide variety of other drugs, whether prescription, non-prescription, legal, or illegal. The tests can also quantify the amount of pain medication or its metabolite present in the urine.[4]

[4] Quantitative results are typically expressed in nanograms of drug or metabolite per milliliter of urine. To adjust for variations in dilution resulting from differing levels of patient hydration, both Millennium and Ameritox "correct" the raw results by making an adjustment based on the sample's creatinine content. Creatinine is a chemical that is produced by the body at a fairly constant rate and filtered from the blood by the kidneys.

Even using this advanced technology, however, UDT has its limitations. First, it provides only a snapshot of current drug use; drugs and their metabolites remain in a person's urine only for so long. Additionally, because individuals metabolize drugs at different rates, UDT cannot determine the dosage taken by the patient or when he took the dosage. During the litigation, Millennium and Ameritox agreed that UDT can determine whether certain drugs are present or absent, but it cannot determine prescription compliance.

As rivals in the UDT industry, Millennium and Ameritox aggressively market their respective services to pain doctors. Their marketing efforts include print and electronic advertisements as well as face-to-face presentations delivered by trained sales representatives.

In 2010, Millennium sued Ameritox under the Lanham Act. Ameritox counterclaimed. The parties accused each other of making false advertising promises. During the course of the litigation, a number of claims and counterclaims were dismissed by the Court or abandoned by the parties. The case that went to the advisory jury only included four Ameritox advertisements that Millennium accused as being literally false under the Lanham Act.[5]

As will be explained in detail herein, the Court asked the advisory jury to examine the accused ads one-by-one from the perspective of a pain doctor. For each ad, the jury was asked whether the advertisement contained the literally false message that Ameritox's services could determine a patient's prescription compliance.

At this point, a brief description of Ameritox's first- and second-generation services, Rx Guardian and Rx Guardian CD is required.[6] The patient provides a urine sample, which the

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[5] Millennium contended in its pleadings that Ameritox's Rx Guardian and Rx Guardian CD services were based on "flawed science." As will be discussed infra, the validity of Ameritox's science was not presented to the jury.

[6] Because none of Ameritox's complaints about Millennium's advertisements reached the jury, there is no need to describe Millennium's UDT services. In describing Ameritox's

doctor forwards to one of Ameritox's laboratories in Midland, Texas or Greensboro, North Carolina. Ameritox first measures the amount of any specified drugs (or their metabolites) present in the patient's urine. Then, Ameritox "normalizes" the patient's results by means of an algorithm to account for the patient's hydration and lean body mass. Finally, Ameritox plots the patient's normalized results against a reference range.

Ameritox describes the reference range as a band within which a prescription-compliant patient's result would be expected to fall.[7] Thus, if a patient has been prescribed 60 mg per day of hydrocodone, Ameritox will compare the patient's normalized score to its "hydrocodone – 60 mg daily dose" reference range. According to Ameritox, 95% of patients who are compliant with their prescription regimens will see their results fall within the applicable reference range. By definition, then, Ameritox also expects 5% of prescription-compliant patients to fall outside the applicable reference range.

Apart from minor changes to its algorithm, the main difference between Rx Guardian and Rx Guardian CD involves the manner in which the reference ranges are derived. The Rx Guardian reference ranges were developed through the research of Dr. Michael Kell. The Rx Guardian CD reference ranges are calculated on an ongoing basis from a database of pain patients being treated at the Marshfield Clinic in Minocqua, Wisconsin.

Millennium's original Complaint accused Ameritox of disseminating false and misleading advertising statements about the capabilities of Rx Guardian.[8] According to

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services, the Court, of course, makes no findings and expresses no opinions concerning their utility. As mentioned, the trial did not test the science behind either Rx Guardian or Rx Guardian CD.

[7] The reference range against which Ameritox compares the patient's normalized score is specific to the prescribed drug and the prescribed total daily dosage.

[8] The Lanham Act prohibits the "false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion,

Millennium, Ameritox falsely advertised that Rx Guardian test results could, by themselves, tell a doctor whether the patient was compliant with his prescription regimen. Ameritox disputed with this reading of its ads, agreeing with the proposition that UDT cannot, by itself, determine prescription compliance. Properly read in context, Ameritox stated, the ads promised only that Rx Guardian afforded doctors with another tool to "help" or "assist" them in monitoring their pain patients.

In the spring of 2011, while the suit was pending, Ameritox transitioned from Rx Guardian to Rx Guardian CD. At that time, Ameritox ceased running advertisements for Rx Guardian and began running advertisements for Rx Guardian CD.

Millennium filed an Amended Complaint challenging certain advertisements for Rx Guardian CD. Millennium contended that the new ads, like the old ads, falsely promised that Ameritox's service could determine prescription compliance. Millennium also added a new claim that focused on Ameritox's description of the patients in the Marshfield cohort as "known to be adherent" to their prescription regimens. According to Millennium, the adjective "known" rendered the advertisements false because the Marshfield patients are not monitored in a controlled in-patient setting. Rather, the Marshfield patients are "assessed" for compliance using a protocol that relies in part on patient interviews and the subjective judgment of clinic staff.[9]

Ameritox denied that the word "known" carries a false connotation. It riposted that, in the context of a growing database that includes over 1,000 patients, any reasonable pain doctor would read "known" to mean "clinically assessed."

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misrepresents the nature, characteristics, qualities, or geographic origin of . . . goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B).

[9] Ameritox agrees that the Marshfield cohort probably includes some non-compliant individuals.

There are two basic ways in which an advertisement can violate the Lanham Act. The advertisement can be either literally false or literally true but misleading. "To constitute a violation of § 43(a) [of the Lanham Act] , . . . 'the contested statement or representation must be either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context.'" C.B. Fleet Co., Inc. v. SmithKline Beecham Consumer Healthcare, L.P., 131 F.3d 430, 434 (4th Cir. 1997) (quoting Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1138 (4th Cir. 1993)).

For an advertisement to be literally false, the falsity must be evident from the face of the ad itself.[10] An advertisement cannot be said to be literally false if the advertising message is ambiguous, meaning that it is susceptible to two reasonable readings, one of which is literally true. Moreover, an advertisement is not literally false if the advertising message is literally true but misleading.

If a plaintiff accuses an advertisement as literally true but misleading, it must offer extrinsic evidence showing that the challenged advertisement tends to mislead or confuse consumers. PBM Prods., LLC v. Mead Johnson & Co., 639 F.3d 111, 120 (4th Cir. 2011). In almost all Lanham Act cases, such extrinsic evidence consists of a scientific survey demonstrating that target consumers were actually misled by the challenged advertising. In rare instances, stark evidence of a defendant's intent to deceive the purchasing public may relieve a Lanham Act plaintiff of its obligation to present evidence of confusion. See Scotts Co. v. United Indus. Corp., 315 F.3d 264, 281 (4th Cir. 2002). In either case, consumer confusion or intent to

[10] When an advertisement is challenged as literally false, the Court reads the advertisement and asks whether it unambiguously conveys a false message. If the answer is yes, then the Court declares the advertisement to be literally false. If the answer is no because the advertisement is ambiguous, then the analysis is more complicated.

deceive must normally be resolved by the finder of fact, meaning a jury unless both sides consent to a bench trial.

As the case stood at the summary judgment deadline, Millennium was challenging five of Ameritox's ads as literally false, two additional ads as literally true but misleading, and a final ad as containing some statements that were literally false and others that were misleading although literally true.

The ads challenged as literally false were:

(1) the "Lifetree Information Sheet," (Rx Guardian),
(2) the "Booth Backdrop Display," (Rx Guardian),
(3) the "Can You Tell…" brochure, (Rx Guardian),
(4) the "Ameritox Elevator Speech," (Rx Guardian), and
(5) the "Rx Guardian CD Fact Sheet." (Rx Guardian CD)

The ads challenged as literally true but misleading were:

(1) the "Know Where They Stand" advertisement (Rx Guardian CD), and
(2) the "The Pain Was Still There" advertisement (Rx Guardian).

The ad challenged as containing both literally false and literally true but misleading statements was:

(1) a page from the Ameritox website (the "Webpage"). The page included a press release announcing the launch of Rx Guardian CD and an accompanying video featuring Ameritox's Chief Medical Officer, Dr. Harry Leider.

The Court's *Daubert* rulings narrowed Millennium's case. The Court granted summary judgment in Ameritox's favor on the ads that Millennium challenged as being literally true but misleading. To demonstrate consumer confusion, Millennium had offered surveys that purported to show significant levels of consumer confusion. The first survey tested the "The Pain Was Still There" ad, and the second survey tested both the "Know Where They Stand" ad and the

Webpage. Both surveys asked pain doctors to look at the challenged advertisements and answer questions about their understanding of the claims made therein.

Ameritox filed a motion in limine to exclude the surveys.[11] After carefully reviewing them, the Court had reservations about their validity and reliability.[12] Significantly, both surveys lacked any meaningful form of control. The Federal Judicial Center's Reference Guide on Survey Research, authored by Dr. Shari Diamond and cited heavily by both parties, describes the purpose and necessity of a control group or question.[13] To be valid, a survey must demonstrate consumer confusion attributable to the challenged advertisement rather than some other source. Absent a proper control, it is nearly impossible to determine how much of the reported confusion is attributable to the survey participants' preexisting beliefs or other background "noise" created when, for example, a participant misunderstands the survey questions or responds to them inarticulately.[14]

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[11] Neither side heeded the advice contained in the Federal Judicial Center's Manual on Complex Litigation that litigants confer in advance regarding survey methodology in order to avoid objections. MCL 4th § 11.493 (Sampling/Opinion Surveys).

[12] Among other concerns, the Court noted that the surveys were not blind. This means that experts who designed, conducted, and interpreted the surveys knew the results hoped for by their client. Moreover, neither expert could explain, in a way that that would allow others to replicate his work, how he coded the doctors' responses as indicating confusion or not. Some responses were so ambiguous that any coding seemed arbitrary. Several other responses seemed to have been miscoded.

[13] Dr. Diamond's Reference Guide on Survey Research is a chapter in a larger work published by the Federal Judicial Center. See Reference Manual on Scientific Evidence (2d ed. 2000).

[14] In this case, the surveys' lack of a proper control to eliminate "noise" was particularly damaging to their credibility. Many consumer surveys involve relatively straightforward advertising claims for simple household products. Such a survey might, for example, test a laundry detergent ad suggesting that the detergent whitens better than bleach. In the instant case, the surveys tested ads for a technical service to determine whether the respondents took away a certain highly nuanced message about the service's capabilities. Absent a control, the surveys could not account for the respondents' pre-existing views concerning the capabilities of UDT.

Moreover, the surveyed advertisements, particularly the "Know Where They Stand…" brochure, contain a significant amount of technical information. Despite this, the survey

To test its preliminary views, the Court engaged Dr. Diamond to serve as a technical advisor.[15] After independently reviewing the surveys, Dr. Diamond opined that they were fatally flawed, primarily because of the absence of proper controls.[16] Based on its independent evaluation of the surveys, which included Dr. Diamond's input, the Court excluded both for failing to meet the standards for admissibility articulated in Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592 (1993).[17]

With no survey evidence, Millennium lacked competent proof that the ads it accused as literally true but misleading had, in fact, misled pain doctors. Accordingly, the Court excluded the "The Pain Was Still There" and "Know Where They Stand" advertisements from the case.[18]

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instructions told the doctors, who were paid up to $125 each to participate, that the survey would take only a few minutes to complete. A number of the responses evidenced a pronounced lack of care in answering the questions. The surveys also failed to determine how the respondents interpreted key words such as "compliant."

[15] The Court wishes to thank Dr. Diamond for her willingness to assist on short notice despite her crowded schedule.

[16] To avoid coloring Dr. Diamond's advice, the Court did not share its concerns with her.

[17] Deprived of the surveys, Millennium sought to invoke an exception to the general rule that a party challenging an ad as misleading must produce evidence of consumer confusion. As stated above, courts have sometimes allowed evidence of the advertiser's intent to deceive to serve as a proxy for evidence of actual consumer deception. This exception is equitable because it spares the victim of a calculated deception the burden and expense of proving that the defendant's transparent effort to mislead was successful. The exception is a narrow one, however. In virtually every false advertising case, the plaintiff alleges conscious deception. Courts must take care, therefore, to ensure that the exception does not swallow the customary requirement that the plaintiff must prove actual consumer deception through extrinsic evidence. For this reason, the exception applies only when there is stark evidence of a knowing and intentional deception. In this case, the Court ruled the exception was inapplicable.

[18] On the eve of trial, Millennium argued that the two ads should proceed to trial because it had challenged them as being literally false as well as misleading. Literal falsity, however, is a matter of law to be decided by the Court. Absent some ancillary factual dispute, it is normally a question to be resolved at summary judgment. Millennium did not move for summary judgment on the "The Pain Was Still There" and "Know Where They Stand" advertisements, and the question of their literal falsity was never briefed. The Court, therefore, determined that Millennium had either insufficiently pled or had waived any argument that the "The Pain Was Still There" and "Know Where They Stand" advertisements were literally false.

The Webpage also fell from the case. Without the proffered survey evidence, Millennium could not prove that the Webpage was misleading. The Court ruled that Millennium could, however, proceed to trial on its accusation of literal falsity, which did not require proof of consumer confusion. Millennium elected to drop its claims against the Webpage, however.[19]

The Court's pretrial rulings also winnowed Ameritox's case against Millennium. After being sued, Ameritox counterclaimed by accusing five of Millennium's advertisements as being deceptive under the Lanham Act:

(1) the "RADAR Report,"
(2) the "Turn-around Time" claim,
(3) the "Next Business Day" claim,
(4) the "LC-MS/MS" claim, and
(5) the "Therapeutic Drug Monitoring" claim.

The Court will consider these claims in turn. Ameritox asserted that Millennium's "RADAR Report" mislead doctors as to the capabilities of Millennium's UDT services. To test consumer confusion, Ameritox commissioned a survey. Ameritox eventually abandoned its RADAR Report counterclaim because the survey showed extremely high levels of "noise" in the marketplace.

Considering the second and third claims, Ameritox contended that Millennium falsely claimed (i) to have the fastest turn-around time in the industry, and (ii) to be able to provide final quantitative lab results by the "next business day." Ameritox sought to support its claims with survey evidence purporting to show physician confusion concerning Millennium's advertisements on these subjects.

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[19] The Court also excluded the "Ameritox Elevator Speech." This internal marketing piece was insufficiently disseminated to the target audience to qualify as "commercial advertising or promotion" under the Lanham Act.

The Court granted summary judgment in Millennium's favor on these two counterclaims, concluding that Millennium's advertising claims were literally true and clear. Ameritox could point to no competing lab that had a faster turn-around time. Ameritox also failed to demonstrate how Millennium's claim that it usually provides results the "next business day" could be false or misleading. Millennium cannot process a urine specimen that it does not have; hence, "next business day" can only mean the day after Millennium receives the specimen. Because the advertising claims are unambiguously true, the Court never had to consider the validity of Ameritox's survey evidence, which purported to demonstrate confusion in how physicians understood the terms "turn-around time" and "next business day." The Court's preliminary review of the surveys, however, identified serious flaws that called their viability into question.

The Court also granted summary judgment in Millennium's favor on the fourth counterclaim issue, finding that Millennium's advertising that it is the only major lab to use exclusively "LC-MS/MS technology" in the processing of samples is accurate. Ameritox could not point to another major lab that tested samples using only LC-MS/MS.

Ameritox's final counterclaim asserted that Millennium's characterization of its services as "therapeutic drug monitoring," or "TDM," was false and misleading. As used in the medical community, the terms properly apply only to drug testing by blood or serum, not urine, Ameritox maintained. The Court denied Millennium's Motion for Summary Judgment, ruling that a dispute of fact existed as to the meaning of "TDM" that could only be resolved by expert testimony at trial. During trial, Ameritox voluntarily dismissed its TDM claim with prejudice, electing not to pursue it.

Thus, none of Ameritox's counterclaims went to the jury. The only ads that were ultimately tested at trial were four Ameritox ads that Millennium challenged as being literally false: the "Lifetree Information Sheet," the "Booth Backdrop Display," the "Can You Tell…" brochure, and the "Rx Guardian CD Fact Sheet."

Before trial, the Court bifurcated the issues of liability and damages, with the liability phase to be tried first.[20] It was contemplated that during the liability phase the jury would first decide several preliminary factual issues.[21] Having done so, the jury would then render an advisory verdict on the literal falsity of each of the four ads. After the jury had returned its

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[20] To succeed on a Lanham Act false advertising claim, a plaintiff must prove five elements:

(1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product;
(2) the misrepresentation is material, in that it is likely to influence the purchasing decision;
(3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;
(4) the defendant placed the false or misleading statement in interstate commerce; and
(5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

PBM Prods., LLC v. Mead Johnson & Co., 639 F.3d 111, 120 (4th Cir. 2011) (citation and quotation omitted).

Though injury is a necessary element of liability, the Court, for practical reasons, deferred the trial of this element until the second (damages) phase. Injury and damages could not easily be separated because both issues would involve substantially the same evidence.

[21] Concerning the "Booth Backdrop Display" and the "Lifetree Information Sheet," the jury was also called upon to decide which materials constituted the "commercial advertisement" for Lanham Act purposes. For the "Rx Guardian CD Fact Sheet," the jury was asked whether the Fact Sheet had been sufficiently disseminated to pain doctors to qualify as a "commercial advertisement" under the Lanham Act. There were no preliminary questions with respect to the "Can You Tell…" brochure.

verdict, the Court would then review the record, including the advisory verdict, and independently decide whether each of the four ads conveyed a message that was literally false.[22]

If the Court found one or more of the ads to be literally false, then the trial would proceed to the second phase, during which Millennium would present evidence of injury and damages. Because injury is a requirement imposed by the statute, a determination of literal falsity in phase one would not, by itself, establish a Lanham Act violation; Millennium would still be required to prove that it had suffered harm. Thus, in phase two, the jury, as the trier of fact, would decide whether the literally false ads had injured Millennium, and, if so, whether to award monetary damages.

During the trial, the Court took pains to explain to the jury what questions were and were not before it. The principal ground rules, which the Court repeated frequently, included the following:

1. This Lanham Act case involved the truth or falsity of the four accused ads. Hence, Millennium could not challenge Ameritox's overall advertising campaign or "brand promise."

2. Because the case focused on the language of the four ads themselves, certain evidence was proscribed as irrelevant, including:
   a. Ameritox's internal sales and marketing material,
   b. testimony regarding Ameritox sales representatives' oral presentations during trade shows and office visits,[23] and
   c. the parties' and their employees' own interpretations of the ads.

3. UDT can determine the absence or presence of drugs and their metabolites. UDT cannot, however, determine whether a patient has been compliant with his prescription regimen.

[22] Decisions regarding literal falsity are made by the judge "as a matter of law." Hence, the jury's verdict was advisory.

[23] In an appropriate case, a scripted oral sales pitch made uniformly by a company's sales force might come within the Lanham Act. The Fourth Circuit Court of Appeals has not decided the viability of this theory. Millennium's evidence on this point would have been insufficient in any event, however.

a. Hence, if an accused ad promised that Rx Guardian, by itself, could tell the doctor whether a patient is taking his pain medication as prescribed, that ad would be literally false.
b. By contrast, if an accused ad promised only that Rx Guardian provides another tool to help or assist a doctor in assessing prescription compliance, that ad would not be literally false.

4. Because the parties agreed that UDT cannot determine prescription compliance, there were no scientific issues for the jury to decide. In other words, the validity of the science behind Rx Guardian or Rx Guardian CD was not presented to the jury. The Court was permitting scientific testimony only as background so that the jury could understand UDT and the products being advertised. Hence, the jury need not decide whether Ameritox's reference ranges actually provide useful information to pain doctors or whether the Marshfield Clinic's assessment protocol was medically sound.

5. The Rx Guardian CD Fact Sheet described the patients in the Marshfield cohort as "known adherent." If a pain doctor would read "known" to mean "clinically assessed" then the ad would be literally true.

6. After answering the preliminary questions, the jury should view the challenged ads from the perspective of a pain doctor.

At the close of the evidence, the Court prepared a simple Verdict Form that framed the questions the jury was asked to decide. After deliberating, the jury found that each of the accused Ameritox ads communicated a literally false message.[24]

Using the advisory verdict as one source of information, the Court independently decided as a matter of law that the challenged advertisements were, in fact, literally false as alleged.

The Court held that the "Booth Backdrop Display," the "Lifetree Information Sheet," and the "Can You Tell…" brochure were literally false because they unequivocally claimed that Rx

[24] The jury decided that the "Rx Guardian CD Fact Sheet," which it deemed to be a commercial advertisement, conveyed "a literally false message about the prescription compliance of the patients in the Marshfield Clinic cohort." With respect to the other three accused ads, the jury determined that each conveyed "a literally false message about the capabilities of the Rx Guardian service."

Guardian could "tell," "verify," or "determine" whether patients were taking their pain medications in the prescribed dosages.

The Court also held that the "Rx Guardian CD Fact Sheet" was literally false because of its description of the Marshfield cohort patients as "known adherent." A reasonable doctor reading the ad would understand that nothing in medicine is ever known with 100% certainty. Thus, a doctor would not expect the word "known" to mean that every conceivable doubt about the patient's adherence had been removed. "Known adherent," however, suggested that the patients had been rigorously monitored in a controlled clinical setting. Instead, the Marshfield protocol only assessed the pain patients to eliminate those who showed certain indicia of non-compliance.[25]

Following these rulings, two issues remained for resolution. First, to establish liability under the Lanham Act, Millennium still needed to prove that the literally false ads had caused injury. If Millennium proved injury, then the Court would consider the appropriate remedy, which might include injunctive relief, damages, or both.

The Court tabled the first issue (injury) but partially resolved the second by ruling that Millennium's case for money damages was too speculative to proceed. As the Court observed supra, monetary damages are often difficult to obtain in Lanham Act cases due to the challenge of tracing monetary losses to specific advertisements. This difficulty is compounded for a company like Millennium, that has enjoyed steady increases in market share and profitability.

[25] At trial, evidence was presented concerning the Lifetree Study, which was funded by Ameritox. The subjects in the study were closely monitored in an inpatient setting. The study is described in the challenged "Lifetree Information Sheet:" "This study evaluated Rx Guardian's ranges with a urine immunoassay . . . for hydrocodone to confirm the participants' prescription compliance. Healthy naltrexone-blocked volunteers were dosed every 6 hours with hydrocodone doses equivalent to 20, 60, and 120 mg per day to steady state." The adjective "known" would be appropriate in this context.

The Court's exclusion of Millennium's damages claim did not, however, impair its ability to seek injunctive relief against Ameritox.[26]

With the remainder of the case thus narrowed, the Court continued the proceedings and arranged for the parties to attend a conference with United States Magistrate Judge Stephanie Gallagher. Following negotiations that lasted long into the night, the parties agreed to a Consent Order that resolved the remaining issues.

Inter alia, the Consent Order provided that Ameritox would no longer state in promotional materials or advertisements that its services can "verify compliance," or "confirm adherence," nor would it use similarly definitive phrasing. The Consent Order also required Ameritox to refer to the patients in the Marshfield database as "clinically assessed to be adherent" rather than "known adherent."

Ameritox was also required to send to its customers and post to its website a letter from its CEO, disclosing the jury's advisory verdict and the Court's ruling that the four challenged advertisements were literally false. The letter would reiterate that "no urine drug test can definitively determine whether a patient has taken the dosage of medication prescribed," and state that pain doctors should "always use their clinical judgment in combination with all available information" in assessing prescription compliance. The parties agreed that the final language of the letter would be subject to pre-approval by Judge Gallagher.

The next day, the Court approved the Consent Order, dismissed the jury, and thanked Judge Gallagher for midwifing the Consent Order. The Court also cautioned the parties that it had no intention of refereeing the advertising war that would likely follow the Order's

[26] Millennium's damages claim faced an additional hurdle; its expert had premised his damages calculations on several questionable sources, including the consumer confusion surveys that the Court had excluded under Daubert.

publication. This proved a vain hope. Hostilities resumed within hours. New suits were filed demanding jury trials and seeking injunctive relief and damages. As mentioned supra, this Memorandum moots the disputes by providing a neutral account of the earlier litigation. The Court will, therefore, by separate order, dismiss all pending cases with prejudice, with each side to bear its own costs.[27]

/s/

Benson Everett Legg
Senior United States District Judge

[27] Much of the record remains under seal. At the Court's request, counsel have helpfully narrowed the list of materials that each seeks to keep under seal. The Court will decide these requests at a brief hearing. Afterward, the Court will issue a final order that unseals all but a small part of the record and closes the case.